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Supreme Court, U.S.
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No. 95-1034

In The

Supreme Court of the United States

October Term, 1995

HUGH ENGLISH, et ux.,

Petitioners,

v.

MENTOR CORPORATION,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF FOR RESPONDENT IN SUPPORT OF THE PETITION

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RESPONDENT'S BRIEF IN SUPPORT OF THE PETITION

SUMMARY

The broadly stated "Question Presented" by the petition (Pet. at i) actually subsumes three discrete questions. The first is whether the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a),[1] trigger preemption of a state law claim alleging defective design of a Class III medical device, where the FDA approved the release of the device to market under that agency's "510(k)" regulatory procedure.

Respondent Mentor Corporation[2] ("Mentor") agrees that the petition should be granted on that question, which is the same one presented in *Mentor Corp. v. Feldt*, No. 95-1037 (pending), and in *Medtronic, Inc. v. Lohr*, No. 95-754, *cert. granted*, January 19, 1996. The two Mentor cases should be consolidated with *Medtronic* for plenary consideration in order that the Court might have the benefit of a record of greater breadth upon which to consider the issue of preemption triggered by the 510(k) regulatory procedure.

Two other Medical Device Act preemption questions were also resolved against petitioner by the court below. These are whether Section 360k(a) also triggered preemption of petitioner's defective manufacturing and failure to

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[1] The text of the statute is printed at Pet. 63.

[2] Pursuant to Rule 29.6, we advise the Court that respondent Mentor has no parent company and no subsidiaries that are not wholly owned.

warn claims, where the device was manufactured in compliance with the FDA's good manufacturing practices regulations, and was marketed in compliance with the agency's labeling regulations.

In the petition in *Mentor Corp. v. Feldt*, Mentor took the position that these two questions concerning preemption of defective manufacturing and failure to warn claims were not cert-worthy because no mature circuit conflict had developed as to those issues. Since Mentor's petition in *Feldt* was filed, this Court granted certiorari to consider the cross-petition in *Medtronic*, No. 95-886. The cross-petition in *Medtronic* appears to present the preemption issues that arise from state law defective manufacturing and failure to warn claims. Thus, the *Medtronic* cross-petition seems to have now placed before the Court for consideration the preemptive consequences that arise from the FDA's good manufacturing practices regulations and the same agency's labelling regulations. In view of the grant of certiorari on the *Medtronic* cross-petition, Mentor would not oppose certiorari in this case for the purpose of also considering whether Section 360k(a) preempts petitioner's defective manufacturing and failure to warn claims, in circumstances where the device was manufactured in compliance with the FDA's good manufacturing practices regulations, and was marketed in compliance with the FDA's labeling regulations.

COUNTERSTATEMENT

This is a product liability case involving the alleged 1992 failure of a penile implant, a Class III medical device manufactured by respondent and installed some years earlier in the person of the petitioner, Hugh English. The case was removed from a Pennsylvania court under the diversity grant. Pet. at 35-36.

Typical of most product liability actions, petitioner's complaint assailed "defects" in the design and manufacture of the device, and also asserted a failure to warn claim. The district court granted summary judgment for respondent on the ground that all three categories of claim were preempted by reason of Section 360k(a) (Pet. at 35-61), and the court of appeals affirmed. *Id.* at 18-34, 62.[3]

The petition is inaccurate, however, in two respects. *First*, petitioner suggests that the 510(k) marketing approval of the FDA was the basis on which the court of appeals found statutory preemption of all three categories of claim. This is not correct. The opinion below makes clear that 510(k) approval triggered preemption of the "design defect" claim, but that the manufacturing defect and failure to warn claims were preempted for other reasons, namely, respondent's compliance with the FDA's good manufacturing practices and labeling regulations, respectively. *See* Pet. at 27-29. The latter is in full accord with other decisions, e.g., *Lohr v. Medtronic, Inc.*,

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[3] The court of appeals reversed the district court's ruling that an express warranty claim was also preempted (*see* Pet. at 33-34), but neither side seeks review of that point here.

56 F.3d 1335, 1350-52 (C.A. 11, 1995), *cert. granted*, January 19, 1996 (Nos. 95-754 and 95-886); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 399-400, (C.A. 4, 1995), *pet'n for cert. pending* (No. 95-1010); *Feldt v. Mentor Corp.*, 61 F.3d 431 (C.A. 5, 1995), *pet'n for cert. pending* (No. 95-1037); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 (C.A. 5), *cert. denied*, 114 S.Ct. 86 (1993).

Second, the petition suggests that because the FDA's 510(k) regulatory process may be somewhat less rigorous than the agency's alternative premarket approval ("PMA") process, the 510(k) process amounts to little more than witless agency approval of "grandfathered" devices. *See* Pet. at 14-16. This innuendo is also inaccurate. The record made in this case shows that respondent's 510(k) application included substantial data as to the safety and efficacy of the device, much of it the product of clinical trials conducted under an earlier-granted FDA Investigational Device Exemption. *See* Pet. at 38, 43-45 (district court's summary of the record before it).

REASONS TO GRANT THE WRIT

Although the question whether 510(k) approval by the FDA triggers preemption of design defect claims is now before the Court in *Lohr*, the Court should grant the petition here on that issue and in the companion case of *Mentor Corp. v. Feldt*, No. 95-1307. Petitioner's argument here, and the court of appeals' decisions in *Lohr* and *Feldt*, *supra*, cast aspersions on the efficacies of the 510(k) approval process. Although such aspersions are wide of the mark, the record in *Lohr* affords only a small glimpse

of the 510(k) process. Plenary examination of the present case, and of *Feldt*, would provide the Court with a record of greater breadth. For this reason, respondent supports and urges the plenary grant of review in this case and in *Feldt* in order to fully consider the question of 510(k) approval.

CONCLUSION

Certiorari should be granted, and the Court should use this case, in combination with *Lohr* and *Feldt*, to consider on a full record whether 510(k) approval triggers statutory preemption of design defect claims as to Class III medical devices.

DATED: February 8, 1996

Respectfully submitted,

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